Robert K. Baldwin
J. Devlan Geddes
Benjamin J. Alke
Jeffrey J. Tierney
GOETZ, BALDWIN & GEDDES, P.C.
35 North Grand
P.O. Box 6580
Bozeman, MT 59771-6580
Phone: (406) 587-0618
Fax: (406) 587-5144
Email: rbaldwin@goetzlawfirm.com
devlan@goetzlawfirm.com
balke@goetzlawfirm.com
jtierney@goetzlawfirm.com

Attorneys for Relators

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA,
BUTTE DIVISION

UNITED STATES OF AMERICA EX REL. FRANK M. REMBERT and MICHAEL R. PARADISE, Relators, v. BOZEMAN HEALTH DEACONESS HOSPITAL, BOZEMAN DEACONESS HEALTH SERVICES d/b/a BOZEMAN HEALTH, and DEACONESS-INTERCITY IMAGING, LLC d/b/a ADVANCED MEDICAL IMAGING, Defendants.	Case No. CV 15-80-BU-SEH **Relators' Response Brief in Opposition to Defendants' Motion for Summary Judgment re: The Elements of Relators' Claims (Doc. 360)**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

OTHER SOURCES

INTRODUCTION

This case presents a classic example of an illegal joint venture. Defendant Bozeman Deaconess Health Services ("BDH") directs referrals to its own joint venture, Defendant Deaconess InterCity Imaging, LLC d/b/a Advanced Medical Imaging ("AMI"). BDH has received cash and other forms of remuneration for those referrals in violation of the Anti-Kickback Statute ("AKS"). 42 U.S.C. § 1320a-7b(b). Claims submitted to the United States as part of a kickback scheme are false or fraudulent claims under the False Claims Act ("FCA"). 42 U.S.C. 1320a-7b(g).

Liability under the AKS ultimately turns on Defendants' intent, i.e. whether they "knowingly" exchanged referrals for remuneration. *U.S. ex rel. Bartlett v. Ashcroft*, 39 F.Supp.3d 656, 676–77 (W.D. Pa. 2014). There is overwhelming evidence they did, including: (1) BDH requested a direct cash payment from non-party Intercity Radiology, P.C.("ICR") for sending referrals to AMI; (2) BDH and ICR negotiated a written agreement ("Side Agreement") concerning the number of referrals to AMI; (3) ICR's attorney advised the Side Agreement was directly contrary to the AKS; and (4) BDH and ICR followed through with the Side Agreement.

Defendants argue the Court should grant summary judgment based largely on Relator Rembert's testimony that he did not believe AMI was

illegal while employed at ICR. That argument ignores plain language of the AKS, which expressly provides that a person need not have actual knowledge of the AKS, or a specific intent to violate the AKS, in order to violate the law. 42 U.S.C. § 1320a-7b(h). It also ignores the facts regarding the formation and operation of AMI and that Relator Rembert is just one witness in a highly complex fraud case.[1]

Defendants' motion for summary judgment should be denied.

BACKGROUND

I. BDH SCHEDULES PATIENTS AT AMI.

Defendants gloss over the nature of their remarkable relationship. AMI is located on the BDH campus, just downstairs from the BDH radiology department. *Statement of Disputed Facts* ("SDF") 213. AMI provides the same outpatient computed tomography (CT) and magnetic resonance (MR) services as BDH. SDF 217–218. AMI leases space from BDH and does not have any of its own employees. SDF 214–216. CT and MR technologists, for example, split shifts between BDH and AMI. SDF 456-457.

Of particular note, AMI does not employ any schedulers. SDF 421. Exams at AMI are scheduled by BDH employees who schedule the exact

[1] Defendants identify two-hundred and eleven (211) separate facts as material to their motion. Doc. 362. Relators dispute many of those and offer additional material facts in response.

same exams in the BDH radiology department. SDF 427. Patients are not typically sent to one location or another for medical reasons. SDF 420–440. Instead, they are directed to the first available appointment, which may be at BDH or AMI. SDF 427, 434-435. BDH requires its employed physicians to use BDH and AMI for radiologic services. *Id*. Referring physicians typically do not specify whether the exam occurs at BDH or AMI, nor do patients typically chose. SDF 429–440. This allows BDH to apportion scans between itself and AMI as it sees fit because it controls things like scheduling protocol, hours of operation, staffing, and equipment, and keeps track of referrals. SDF 447–472.

BDH's contention that centralized scheduling "is a common practice in the industry" is highly misleading. Doc. 361, p. 9. Tom Greeson, ICR's attorney, is former counsel for the American College of Radiology and specializes in advising radiologists. SDF 446. He has advised clients in all fifty states and the District of Columbia, but is unaware of a similar arrangement anywhere in the country. *Id*.

Greeson's notion that this is an unusual arrangement is consistent with guidance provided by the U.S. Department of Health and Human Service Office of Inspector General ("HHS-OIG") regarding healthcare joint ventures, which warns hospitals contemplating joint ventures to "scrutinize

the venture with care." To reduce (but not eliminate) the risk of fraud and AKS violations, HHS-OIG advises hospitals to "at a minimum,"

> (1) bar employed physicians from referring to the joint venture;
>
> (2) avoid exerting any pressure on or encouraging, "in any manner," affiliated medical staff to refer to the joint venture;
>
> (3) memorialize the above policies in writing;
>
> (4) not track referral volumes and sources;
>
> (5) disclose the hospital's financial interest in the joint venture to patients; and
>
> (6) require other participants in the joint venture to adopt similar measures.

70 Fed. Reg. 4858, 4866. (Jan. 31, 2005). AMI violates each of those "minimum" requirements.

AMI does not qualify for any of the "safe harbor" regulations promulgated by the HHS-OIG (42 C.F.R. § 1001.952(a)(2)), because (i) BDH is in a position to generate referrals for AMI and owns more than 40% of the joint venture; (ii) BDH was offered an investment interest related to its expected volume of referrals; and (iii) more than 40% of AMI's gross revenue come from referrals or business generated by BDH.

As explained below, Mr. Greeson advised that the formation of AMI was illegal based on the Side Agreement—regarding the scheduling

system he testified that he did not "know the details of it at all." SDF 441.

II. BDH USED REFERRALS TO OBTAIN A MAJORITY INTEREST IN AMI AND AVOID COMPETITION.

In 2002, ICR hired a consultant, AGI, to study the feasibility of opening an independent imaging facility in Bozeman, Montana. SDF 220. ICR considered partnering with a hospital or other group in an outpatient center and eventually offered BDH the opportunity to participate on a 50-50 basis. SDF 221–223. That imaging center would not have relied upon patients contributed by BDH. SDF 224–225.

BDH derailed that threatened competition by giving ICR an exclusive contract to provide radiology services to the hospital's patients. SDF 226–228. The exclusive contract prohibited ICR from participating in a joint venture without BDH. SDF 228.

[redacted] BDH then used the leverage it had by virtue of its position to generate referrals to negotiate a 77.5% ownership interest and control over AMI. SDF 244–254.

According to BDH "[t]he pros of the joint venture would be an

alignment with the radiologists that would reduce the possibility of future competition and the giving up of part of the business is better than giving up more." SDF 267. Partnering with ICR also allowed BDH to designate AMI as a physician clinic for the purposes of Medicare reimbursement, which at the time in 2004-2005, reimbursed at a higher rate than exams performed in a hospital outpatient department. SDF 255–264.

III. BDH VALUED THE PATIENTS IT INTENDED TO REFER TO BDH AND REQUESTED PAYMENT FOR THOSE PATIENTS.

BDH then hired Value Management Group, LLC ("VMG") a Texas company, to perform further valuations. SDF 268. According to the draft VMG report from October 2004 "[b]ased on management representations, the Hospital will contribute business operations including approximately 18,517 outpatient imaging scans to the proposed joint venture." SDF 272. VMG calculated that AMI would be worth approximately $2.6 million based on projected patient exams. SDF 273–275.

Then, in direct violation of the AKS, BDH solicited payment from ICR for referrals. A January 2005 email from David Monaghan, the practice administrator of ICR who led negotiations with BDH, to Greeson, states:

> Thus, Intercity Radiology has to pay the hospital (not the joint venture) 22.5% of the discounted cash flow projections (some 600k) to the hospital because they are essentially buying that share of the business from the hospital because the **"patients are the hosp-**

> **itals."**… I was told in a serious tone this was a deal breaker.

SDF 278 (emphasis added).

Greeson advised ICR that BDH's proposal was illegal. *SDF* 285–296 ("Our attorney believes purchasing the revenue stream is illegal). Greeson communicated those concerns to BDH. *SDF* 297–298

IV. BDH AND ICR NEGOTIATED A SIDE AGREEMENT OVER REFERRALS.

BDH did not heed that warning. Instead, BDH and ICR negotiated a Side Agreement regarding the amount of referrals. SDF 312–334. A draft of the Side Agreement specifically states that "[t]he intent is to ensure that all OP volume is not shifted from the hospital to the OP center."

Greeson advised that the Side Agreement was also illegal. An email from Monaghan relayed Greeson's advice that the Side Agreement "reflects his point about buying referrals." SDF 323. An May 4, 2005 email from Greeson about draft language in the Side Agreement stated:

> I am concerned with this suggested language. Frankly, I'm hoping we can eliminate the need to discuss volumes in any manner. We feel strongly that the valuation should not be changed if any volume assumptions later turns about to be incorrect. If the valuation changes, then the contributions are no longer based on value unrelated to referrals but on referrals and the resulting revenue stream which is **directly contrary to the antikickback statute**.

SDF 328 (emphasis added).

Monaghan testified that he understood a limit on volume would be "slam dunk" illegal. SDF 330.

V. BDH AND ICR REACHED AN AGREEMENT ON REFERRALS.

Despite the fact that an agreement on volume would be "directly contrary to the antikickback statute" and "slam dunk" illegal, that is exactly what Defendants did.[2] SDF 335–348.

Meeting minutes from May 24, 2005, three weeks after Greeson warned against a Side Agreement over volume, state "**What we have generally or specifically conceded to**: 1) Limiting CT volume @ 12 patients a day (unless they do more than 12 then we can do more." SDF 336 (emphasis in original).

The volume limits in the Side Agreement were specifically incorporated into the final valuation prepared by VMG in May 2005, which formed the basis for contributions to the joint venture. SDF 339–344. The final valuation calculated the fair market value range of AMI to be between $700,000 and $770,000 based on cost of equipment, but the income

[2] In support of its motion, BDH repeatedly represents that BDH and ICR had separate counsel that that ICR complied with the advice of its lawyers. SDF 71, 72, 88, and 89. Aside from the fact that statement contracts the documentary evidence, it is an improper attempt to invoke advice of counsel as a defense.

approach, based reflecting the agreed upon 12 patients a day at 1.4 scans per patient (16.8) resulted in essentially the same value. *Id*. BDH meeting minutes from May 24 explain what happened:

> At the same time the valuation was pending, we were talking with the radiologists about restricting the number of CT scans to the center in order to preserve hospital volume. We agreed to expect an average of 17 CT scans per day for the center. This decrease in number of CT scans changed the type of valuation from an income to cost based approach.

SDF 337.

The agreement to restrict volume confirmed that referrals from BDH to AMI was part of the agreement related to the joint venture—in direct violation the AKS. BDH and ICR memorialized the agreement in the signed Side Agreement.[3] SDF 357–366.

VI. BDH FOLLOWED THROUGH WITH THE AGREEMENT ON REFERRALS.

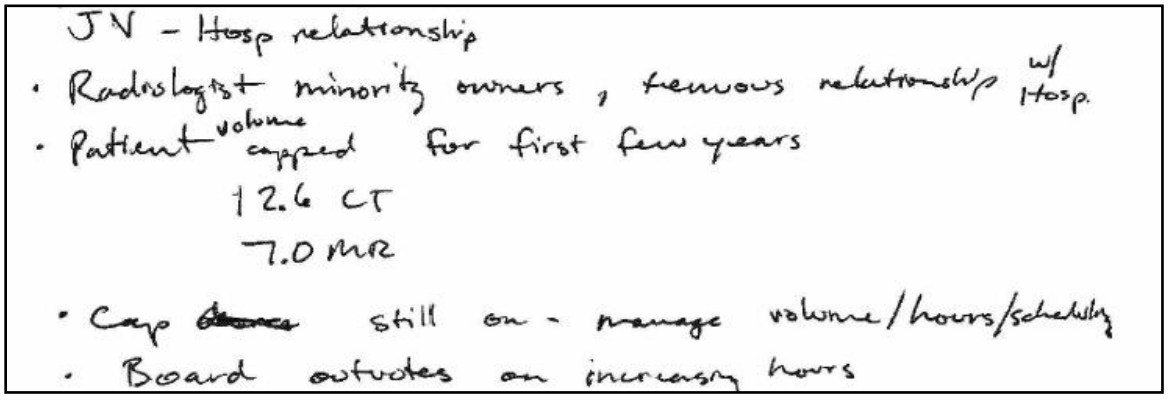
When AMI began operations, its "budget" for the number of patient exams that it could perform was based on the Side Agreement and the

[3] Although the Side Agreement is dated May 4, 2004, evidence suggests that the Side Agreement was signed at the same time as the AMI Operating Agreement. SDF 357–366. For example, a later email from Monaghan to Lewis, containing a spreadsheet with comments on all the joint venture agreements including the Side Agreement, states "I will try and meet with Gordon early next week so by mid-next week we can finalize and sign all of the agreement together." SDF 363.

related 2005 VMG valuation. SDF 407–416. Meeting minutes of ICR and AMI refer to the Side Agreement for volume expectations. SDF 407–411.

Relator Paradise began working at ICR in 2007. During his interview, Paradise was told the hospital was limiting studies at AMI. SDF 392–400. Notes he took around that time confirm those conversations. SDF 394–399.Paradise was unaware of the Side Agreement and other documents and discussions related to the formation of AMI during his employment, but he knew volume was restricted. SDF 401 He first saw the Side Agreement when BDH produced a copy in state court litigation. SDF 404-405.

Then, in 2009, AMI hired VMG to conduct another valuation of the imaging center. SDF 367–391. Handwritten notes taken by VMG during that valuation, arising from a conversation with Courtney Funk, provide the "smoking gun" proof of Defendants' illegal scheme.



SDF 382. Defendants cannot credibly dispute that there was an agreement regarding volume. Even if they could, that would merely present a triable

fact issue that precludes summary judgment.

VII. BDH USED ITS CONTROL OVER AMI TO ENFORCE THE LIMIT.

BDH was able to enforce the limit at AMI because of its control over every aspect of AMI's operations. In addition to scheduling, BDH controlled staffing at AMI. SDF 451, 456–459. It controlled AMI's hours of operation and its ability to purchase new equipment. SDF 460–472. Liz Lewis, the chief operating officer of BDH who negotiated the Side Agreement, is responsible for operations in BDH's radiology department, and is on the operating committee of AMI. SDF 302–305.

BDH also controlled pricing at AMI. It required AMI to charge the same amount for exams in order to preclude patients from having a cheaper option, since that could potentially influence where they received treatment. *SDF* 473–479. According to an email from Courtney Funk in 2010 "[w]e direct where patients receive their CT and MRI services" so difference in prices "represents an ethical problem with where we schedule patients." SDF 479. AMI avoided this "ethical problem" by making sure that both BDH and AMI charged the same high rates. *Id*.

SUMMARY JUDGMENT STANDARDS

Summary judgment is proper only if there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.

Fed.R.Civ.P. 56(a). The governing substantive law determines which facts are "material," i.e. whether they might affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute is "genuine" if there is conflicting evidence or multiple inferences might be drawn from the evidence such that a reasonable jury could find for the non-movant. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986).

The purpose of Rule 56 "is not to cut litigants off from their right of trial by jury if they really have issues to try." *Poller v. Columbia Broad. Sys.'s, Inc.*, 368 U.S. 464, 467 (1962). Summary judgment is not "a substitute for trial on the facts and law." *Cox v. English-American Underwriters*, 245 F.2d 330, 339 (9th Cir. 1957). Thus, the court may not weigh the evidence or make credibility determinations and must draw all reasonable inferences in favor of the non-movant. *Liberty Lobby*, 477 U.S. at 248.

"[L]arge, complex cases with multiple parties may be less amenable to summary judgment by their very nature…" because disputes involving "numerous fact-specific issues and dauntingly voluminous records" rarely fit Rule 56's narrow rubric.11 *Moore's Federal Practice*, § 56.25[2][a]; *see, e.g., Marketquest Grp., Inc. v. BIC Corp.*, 862 F.3d 927 (9th Cir. 2017). In evaluating intent, "[c]ircumstantial evidence is not only sufficient, but may

also be more certain, satisfying and persuasive than direct evidence." *Desert Palace, Inc. v. Costa*, 539 U.S. 90, 100 (2003) (this principle is "clear and deep rooted"). Deciding intent on summary judgment often violates the prohibition on weighing evidence and requires the Court to draw impermissible inferences favoring the movant. Moore, § 56.25[2][b]. Courts exercise particular caution with respect to questions of intent…" because the jury may draw a variety of permissible inferences from the evidence. *Id.*; *see also S.E.C. v. Seaboard Corp.*, 677 F.2d 1289, 1296 (9th Cir. 1982) (in a fraud case, "when intent is at issue, the court should be cautious in granting summary judgment.").

In an AKS-FCA case, which sounds in fraud and turns on intent, no "smoking gun" is required. *U.S. ex rel. Pogue v. Diabetes Treat. Cntrs. of Am.*, 565 F.Supp.2d 153, 162 (D.D.C. 2008). Summary judgment should be denied if there is "sufficient circumstantial evidence to create a jury question as to whether a defendant violated the AKS." *Id.*

Summary judgment is also inappropriate where, as here, there are undecided discovery motions seeking information that might help show there is a triable dispute. *See, e.g., Morgal v. Maricopa Cnty. Bd. of Super.'s*, 442 Fed. App'x 246 (9th Cir. 2011); *Clark v. Cap. Credit & Collect. Serv.'s, Inc.*, 460 F.3d 1162 (9th Cir. 2006).

DISCUSSION

I. DEFENDANTS ACTED KNOWINGLY AND WILFULLY.

A. Defendants apply the wrong standard. Intent to violate the law is not required.

The AKS makes it illegal to knowingly solicit or receive payment in any form in exchange for referrals. 42 U.S.C. § 1320a-7b(b). As this Court explained, the AKS "is broadly interpreted to cover any arrangement where one purpose of remuneration is to obtain money for the referral of services or to induce future referrals." Doc. 71, p. 6 (quoting *U.S. v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985)).

Defendants claim they are entitled to summary judgment because Relators cannot prove they "intended to violate the law." Doc. 361, p. 21–22 (citing *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), which held that the AKS requires proof of "specific intent to disobey the law."). In a footnote, Defendants state that the *Hanlester* intent standard was "slightly modified" by a statutory amendment in 2010. The amended statute says "**a person need not have actual knowledge of this section or specific intent to commit a violation of this section**." 42 U.S.C. § 1320a-7b(h) (emphasis added). Congress did not "slightly modify" *Hanlester*. Congress abrogated *Hanlester* because its heightened scienter standard gave undue protection to perpetrators of healthcare fraud.

Prior to *Hanlester*, the Ninth Circuit held that the necessary intent to exchange prohibited kickbacks exists when "one purpose of the payment" is to induce referrals, even if there are other reasons. *U.S. v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (quoting *Greber*); *accord U.S. v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000); *Bartlett*, 39 F.Supp.3d at 676–77 (under *Greber*, a relator must "prove that a defendant knowingly and willfully received or solicited remuneration where at least one purpose…was to induce referrals…."); *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F.Supp.3d 460, 468 (D.S.C. 2016) ("in FCA cases involving AKS violations, courts have found scienter where one purpose of the remuneration was to induce referrals."). The inquiry focuses on the intentionality of the transaction—not violation of the law—consistent with the statute's pairing of the intent element with its prohibition on the solicitation or receipt of remuneration. *See* 42 U.S.C. §1320a-7b(b)(1).

Contrary to Defendants' suggestion,[4] Congress's exclusion of a specific intent requirement controls regardless of the timing of the claims relative to the 2010 amendment. The amendment was only a clarification. *See* 155 Cong. Rec. S10853 (the amendment "addresses confusion" and

[4] *See* Doc. 21, p. 14, n. 1, suggesting that § 1320a-7b(h) applies only to "claims accruing after 2010."

"clarifies"); 155 Cong. Rec. S13692–93 (it "clarifies the intent requirement…to facilitate effective, fair, and vigorous enforcement."); *U.S. v. Ferrell*, 2013 WL 2636108, at *3 (N.D.Ill. June 12, 2013) (Congress "simply clarified" what it had intended). Clarifying, as opposed to substantive, amendments are retroactive because they are "statement[s] of what [the statute] has meant all along." *ABKCO Music, Inc. v. LaVere*, 217 F.3d 684, 691 (9th Cir. 2000); *see, e.g., U.S. ex rel. Brown v. Celgene*, 226 F.Supp.3d 1032, 1053 n.24 (C.D. Cal. Dec. 28, 2016) (finding "no retroactivity concerns" in applying post-2010 AKS provisions to pre-2010 conduct).

Congress has made clear that knowledge of the facts comprising the violation of the AKS is sufficient to establish intent because the "giving or taking kickbacks is hardly the sort of activity a person might expect to be legal…." *U.S. v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998); *see also U.S. v. Wijegunaratne*, 2013 WL 5274409, at *1 (C.D. Cal. Sep. 18, 2013); *U.S. ex rel. Armfield v. Gills*, 2012 WL 12918277, at *5 (M.D. Fla. Oct. 18, 2012). Bargaining with patients is "clearly *malum in se*," *Starks*, 157 F.3d at 838, so a finding of an intentional solicitation or exchange of remuneration for referrals is sufficient to establish intent.

Defendants' statement of the issue—whether there is proof they

"knowingly and willfully enter[ed] into an illegal kickback scheme" or "intended to violate the law"—applies the wrong legal standard.

B. Under any standard, there is abundant evidence from which a reasonable jury could infer intent.

There is ample evidence that "one purpose" of forming AMI was to facilitate the exchange of remuneration for patient referrals to support a jury verdict finding intent:

- BDH intended to contribute patients to AMI (SDF 220–254);
- BDH obtained a 77.5% ownership interest by virtue of its ability to contribute patients (SDF 237–254);
- BDH valued the patient referrals (SDF 265–276);
- BDH solicited payment from ICR for those referrals (SDF 277–279);
- Greeson communicated that was illegal (SDF 280–295);
- BDH and ICR negotiated a Side Agreement over referrals (SDF 312–324);
- Greeson communicated the Side Agreement was illegal (SDF 236–330);
- BDH and ICR entered the Side Agreement (SDF 335–344);
- BDH and ICR followed through with the Side Agreement (SDF 382);

- BDH manipulates volume at AMI and directs where patients receive their scans (SDF 407–472).

Any one of those facts alone would be sufficient to prove Defendants' liability at trial, let alone avoid summary judgment. *See e.g. U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 380 (4th Cir. 2015) (evidence that attorney advised defendants of illegality was "alone sufficient to sweep aside" a claim of error as to intent).

C. No single witness or document is dispositive of intent.

Defendants emphasize Relator Frank Rembert's deposition testimony as proof that Defendants did not intend to violate the law. Of course, what Relator Rembert knew is not the same as what BDH, ICR, or AMI knew. Relator Rembert is a single witness and one of a number of individuals involved in the negotiation, planning, and implementation of AMI. The jury is free to give his testimony whatever weight that it will, in consideration of the documentary evidence and the testimony of other witnesses.

Moreover, Relator Rembert did not think the AMI deal was illegal is because he was not fully informed. Relator Rembert testified it was his belief that people like David Monaghan and Liz Lewis, who were negotiating the agreements, had vetted the legality of the arrangement but it was now clear to him that was not the case. SDF 349.

In any case, whether Relator Rembert knows whether anyone

intended to violate the law ignores the plain language of the AKS. 42 U.S.C. § 1320a-7b(h). The issue is not whether Rembert recognizes the illegality of the scheme based upon the information Lewis and Monaghan gave to him. Instead, the issue is whether Defendants knowingly exchanged referrals for remuneration. 42 U.S.C. § 1320a-7b(b). On that issue, Relator Rembert testified that BDH and ICR did reach an agreement over referrals to AMI. SDF 345 ("I thought this was an agreement for a volume of patients that would [be] contributed to AMI."). Relator Rembert believed the Side Agreement dictated patient allocation. SDF 345–349.

Defendants' focus on the Operating Agreement is also misplaced. As explained in Relators' response to Defendants' motion in limine on this issue (Doc. 357).[5] Defendants cannot use the Operating Agreement to conceal the underlying the fraud. *See, e.g., McClatchey*, 217 F.3d at 830 (a jury could "infer that McClatchy directed McGrath and legal counsel to address the service issue merely to insure that the final contract appeared on its face to constitute a legal arrangement.").

II. DEFENDANTS EXCHANGED REFERRALS FOR REMUNERATION IN VIOLATION OF THE AKS.

Defendants next argue Relators have failed to prove that Defendants

[5] As further explained in Doc. 357 and in note 3, *supra*, there is also a factual dispute about when the agreements were signed.

actually solicited or received remuneration. Doc. 27, pp. 27–38. In this case, where there is a written and signed agreement allocating a certain volume of patients and specifying various *quid pro quos*, this argument borders on frivolousness. Remuneration is broadly defined under the AKS and there is substantial evidence from which a reasonable jury could find it.

A. Remuneration is broadly defined as anything of value.

Consistent with the purpose of the AKS, to root out fraud in any form, "remuneration" is defined extremely broadly. "Congress, concerned with escalating fraud and abuse in the Medicare–Medicaid system," amended the AKS in 1977 "to strengthen the government's ability to prosecute and punish fraud" by adding language broadly prohibiting the solicitation or receipt of "**any remuneration**" in exchange for referrals or to induce future referrals. *Hanlester*, 51 F.3d at 1396 (emphasis added). This "broad term" was employed to "broaden the reach of the law" and make clear that the statute extends to any benefit or thing of value and not just traditional "kickbacks, bribes, and rebates." *Id.* at 1398.; *see also U.S. ex rel. Jacobs v. CDS, PA*, 2015 WL 5698395, at *4 (D. Idaho Sep. 28, 2015) (remuneration is "broadly defined" subject to enumerated exceptions); *Bartlett*, 39 F.Supp.3d at 677 ("remuneration can include anything of value…and in any form….").

Defendants' notion that "remuneration" can only exist when there has been an inequivalent or unreasonable exchange is contrary to well-settled law. The AKS is violated if "one purpose" of the remuneration is prohibited, even if the other purposes are entirely fair and legitimate.

> The text [of the statute] refers to "any remuneration." That includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended.…By including such items as kickbacks and bribes, the statute expands "remuneration" to cover situations where no service is performed. That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist.

Greber, 760 F.2d at 71; *see also, e.g., Bartlett,* 39 F.Supp.3d at 677–78 (denying summary judgment based on fact that remuneration was consistent with fair market value, which was relevant to safe harbor eligibility but not dispositive of liability). The fact that remuneration is fair or "reasonable" is not dispositive because it does not answer whether "one purpose" of the remuneration was to induce referrals. *U.S., ex rel. Solis v. Millennium Pharm., Inc.*, 2015 WL 1469166, at *6 (E.D.Cal. Mar. 30, 2015).

B. There is substantial evidence from which the jury could find that valuable remuneration was solicited and received.

The evidence in this case shows that Defendants negotiated over how to compensate BDH for the stream of patients it would contribute to

the joint venture. Defendants argue that the undisputed evidence shows there was no agreement to exchange remuneration for referrals. The Side Agreement and overwhelming evidence say otherwise.

Even apart from the Side Agreement, the evidence shows that the original plan for the joint venture was a 50-50 allocation of ownership between ICR and the hospital. SDF 220–254 But, once negotiations over volume and revenue projections began, that allocation changed to a 77.5% majority ownership interest in favor of the hospital. *Id.* BDH solicited and received a number of valuable benefits in exchange for the patients it "contributed" to AMI, including:

- An oversized ownership interest resulting in hefty pro rata compensation for every scan performed at AMI;
- The ability to recapture the hospital's own overflow (i.e. after filling up its own department where BDH received 100% of the profit, sending the remainder to AMI where BDH would get 77.5%);
- Control over the joint venture, including issues like insurance contract negotiations, pricing, and scheduling; Elimination of potential competition both externally and internally (i.e. the radiologists themselves, via contractual non-

competes and disincentivizing competition by cutting ICR in on the technical component of the hospital's business); and

- Various free services including but not limited to uncompensated medical directorships and supervision of hospital employees stationed at the joint venture.[6]

Any one of these valuable benefits if enough to find remuneration.

III. MATERIALITY UNDER THE FCA IS ESTABLISHED AS A MATTER OF LAW. OR, AT A MINIMUM, THERE IS A TRIABLE ISSUE.

Defendants next argue that, even if they did violate the AKS, Relators cannot prove that their misrepresentation of compliance was sufficiently "material" to establish an FCA violation. This argument contradicts well-settled law and the plain language of the AKS. Claims for payment resulting from AKS violations **are** false claims by definition. 42 U.S.C. § 1320a-7b(g).

A. AKS certification is material as a matter of law.

Defendants "materiality" argument based on *Univ. Health Serv.'s, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989 (2016), is inapt. *Escobar* held that an implied false certification claim under the FCA requires a misrepresentation that is "material" to the government's decision to pay the claim, and the fact that the government designated something as a

[6] For example, AMI pays for a BDH employee to provide free services at AMI and direct cancer patients back to BDH for treatment. SDF 480–488.

"condition of payment" is not always dispositive. *Id.* at 1993–94. In other words, even when compliance with a condition is technically required such that the government *could* decline payment—like *Escobar's* example of a shipment of foreign-manufactured staplers when the contract called for American-made—treating every little misrepresentation as a fraud against the government would result in absurdities. *Id.* at 2004. Sometimes misrepresentations are sufficiently trivial that the government still *would* pay. Thus, the Court explained, the materiality requirement screens out "minor or insubstantial" violations in contrast with violations of requirements that are "central" to a government program's operation. *Id.*

Escobar was not an AKS case and did not purport to answer whether AKS violations are "material." Congress has already done so. The AKS, as amended in 2010, provides:

> In addition to the penalties provided for in this section …a claim that includes items or services resulting from a violation of this section **constitutes a false claim** for purpose of subchapter III of chapter 37 of title 31 [i.e., the False Claims Act].

42 U.S.C. § 1320a-7b(g) (emphasis added). Numerous courts, before and after *Escobar*, have held that this language validates what the courts have long recognized: compliance with the AKS is always material.

For example, the Fourth Circuit cited the above provision to explain

that "[a]n AKS violation that results in a federal health care payment is a **per se false claim under the FCA**." *U.S. ex rel. Lutz v. U.S.*, 853 F.3d 131, 135 (4th Cir. 2017) (emphasis added). The trial court in the same case performed a detailed post-*Escobar* analysis of the materiality requirement. Surveying numerous AKS-FCA cases, it concluded that "AKS compliance was *per se* material even before the PPACA [amended the AKS in 2010]." *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 2017 WL 6015574, at *1 (D.S.C. Dec. 4, 2017). It was already clear that an AKS violation is not "*de minimis*" or a "mere technical violation" of "fine print," but a potential felony on a matter of central importance to healthcare and government insurance programs. *Id.* at *2. The 2010 amendment then eliminated any uncertainty by signaling "Congress's intent that AKS compliance is material to payment decisions in **all cases**…." *Id.* (emphasis added).

As this Court explained, AKS compliance is a "precondition of Medicare payment." Doc. 71, pp. 6–7. AKS compliance is not an "extraneous condition" but an "essential feature" of Medicare, of the kind *Escobar* recognized may be "so central to the functioning of a government program that noncompliance is **material as a matter of law**." *Celgene*, 226 F.Supp.3d at 1049 (emphasis added) (citing *Escobar*, 136 S.Ct. at 2004). *see also U.S. ex rel. Brooks v. Trillium Cmty. Health Plan, Inc.*, 2016 WL

1725300, at *7 (D.Or. Apr. 29 2016) (AKS certification is a "*sine qua non* of receiving funding"); *Jacobs*, 2015 WL 5698395, at *11 (Congress "eliminated any doubt" that AKS compliance is a "precondition to the payment of Medicare *and* Medicaid claims."); *accord U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 41 F.Supp.3d 323, 331 (S.D.N.Y. 2014) (AKS compliance is not "merely a condition" but an essential "precondition" of participation and payment).

Trial courts in the Ninth Circuit consistently find that claims made upon false certifications of AKS compliance are false claims, without further proof of materiality. For example, *Celgene* rejected a motion for summary judgment on materiality in an AKS-FCA case. The court balked at the movant's notion that the relators were required to offer extrinsic proof of materiality in an AKS case, calling it a "misread[ing]" of *Escobar*, which "le[ft] undisturbed cases in this circuit and elsewhere holding that a claim is 'false' if it is statutorily ineligible for reimbursement." *Celgene*, 226 F.Supp.3d at 1044–45 (citing *Ebeid ex rel. U.S. v. Lungwitz,* 616 F.3d 993, 1001 (9th Cir. 2010)); *U.S. ex rel. Mateski*, 2017 WL 1954924 (C.D. Cal. Feb. 10, 2017) (*Escobar* left *Ebeid* "intact"); *see also Rose v. Stephens Inst.*, 2016 WL 5076214 (N.D. Cal. Sep. 20, 2016) (*Escobar* does not apply to "every single implied false certification claim."); *U.S. ex rel. Wood v.*

Allergan, Inc., 246 F.Supp.3d 772 (S.D.N.Y. 2017); *U.S. ex rel. O'Donnell v. Am. at Home Healthcare*, 2017 WL 2653070 (N.D. Ill. Jun. 20, 2017).

Because *per se* materiality was already the law of the Ninth Circuit, *see Ebeid*, *supra,* there is no retroactivity problem and § 1320a-7b(g) controls regardless of timing of the claims relative to the amendment. Even if the 2010 amendment had marked a departure from Ninth Circuit law, this was another clarifying amendment entitled to retroactive effect. *See U.S. ex rel. Brown v. Celgene*, 2014 WL 3605896, at *7 (C.D. Cal. Jul. 10, 2014) ("The amendment merely clarified existing law…" and, in any case, most courts already "consistently held that non-compliance with the AKS rendered a claim non-payable….").

B. Even if materiality were an issue, it would be unsuited to resolution on summary judgment.

If the Court does not conclude materiality is established as a matter of law, summary judgment is still improper. While *Escobar* indicated materiality can sometimes be resolved by summary judgment, it is often "a fact-intensive and context-specific inquiry." *New York v. Amgen, Inc.*, 652 F.3d 103, 111 (1st Cir. 2011); *accord U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 2017 WL 3773276, at *3 (D.S.C. Aug. 29, 2017) (materiality may present a jury question); *Shin v. U.S.*, 2017 WL 2802866, at *9 (D. Haw. Jun. 28, 2017).

In cases where materiality is not established as a matter of law, the "crux" of the inquiry is whether the misrepresentation was significant enough to influence the government's decision to pay the claim. *Waldmann v. Fulp*, 259 F.Supp.3d 579, 607 (S.D. Tex. Oct. 12, 2016). Relators have offered reimbursement and billing expert Cris Miller to educate the jury about the kinds of certifications involved in Medicare enrollment and claims submission. *See* Doc. 234-3, pp. 11–13. The fact that compliance is a designated condition of participation and payment is relevant even when it is not dispositive. *Escobar*, 136 S.Ct. at 2003. Other courts have held that materiality can be established by testimony showing that the defendants knew and understood that payment was "conditional on compliance with the requirement at issue." *U.S. ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647 F.3d 377, 394 (1st Cir. 2011).

Defendants argue that their conduct must have been immaterial because the government has continued to pay. But, since *Escobar*, the Ninth Circuit has warned against "read[ing] too much into" continued payment, which would allow defendants to use ongoing fraud as a "shield" against liability. *U.S. ex rel. Poehling v. UnitedHealth Group, Inc.*, 2018 WL 1363487 (C.D. Cal. Feb 12, 2018) (discussing *U.S. ex rel. Campie v. Gilead Sci., Inc.*, 862 F.3d 890 (9th Cir. 2017)).

The government's decision to pay a claim is only probative of materiality if the government has "actual knowledge" of the violation. *Escobar*, 136 S.Ct. at 2003. The government is still investigating this case and it has not yet been adjudicated that Defendants actually violated the AKS. "General suspicions" that remain unproven are not the same as "actual knowledge" showing the government believes the violation is immaterial. *Poehling*, 2018 WL 1363487, at *12; *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 2017 WL 4803911 (D.S.C. Oct. 23, 2017) (government did not have actual knowledge of an AKS violation while it was investigating).

Notably, none of the cases Defendants cite are AKS cases. Instead, they involve straightforward misrepresentations about products and services in traditional FCA cases where the government's "knowledge" of the misrepresentation did not depend on an underlying, unadjudicated, intent-based violation. *See, e.g., U.S. ex rel. Marshall v. Woodward,* Inc, 812 F.3d 556 (7th Cir. 2015) (misrepresentation about helicopter parts) *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017) (misrepresentation about "headcount" data at government recreation center); *U.S. ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017) (misrepresentation about cost reports in government service contract).

In the healthcare setting, "[t]he Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing." *Lutz*, 2017 WL 4803911, at *7 (concluding that an AKS defendant's denial of scienter contradicted and precluded materiality argument alleging government had actual knowledge of the violation). This situation is nothing like the *Escobar* example where the government could choose to repudiate the non-conforming stapler shipment if the "Made in China" stamp was material, or ignore it and tender payment if it was not. Continued payment during the pendency of this case is irrelevant.

If the Court concludes that continued payment is relevant at all, it is merely "evidence" of immateriality. *Escobar*, 136 S.Ct. at 1995; *see also Celgene*, 226 F.Supp.3d at 1050. The jury would have to weigh that evidence against all of the other evidence bearing on the scope and severity of Defendants' conduct. A reasonable jury could certainly find, as the court in *Wood* put it, that this case is a "far cry" from the kinds of insubstantial misrepresentations that fail the materiality test under *Escobar*.

IV. CAUSATION IS NOT AN ISSUE UNDER THE FCA EITHER. OR, AT A MINIMUM, THERE IS A TRIABLE ISSUE.

Finally, Defendants argue that Relators have failed to prove that Defendants' false claims to the government were caused by their AKS violations. Defendants overstate the necessary proof of "causation" in an

FCA case, which in any case is more than satisfied.

A. The only required proof of "causation" is that Defendants caused false claims to be submitted.

The kind of "causation" Defendants discuss, i.e. that the kickback "caused" a reimbursable claim for payment, is not an element of Relators' claims at all.

The FCA only discusses causation in the sense that a defendant may be liable if it "causes" a false claim to be presented, as well as for directly presenting the claim. 31 USC § 3729(a)(1); *see U.S. v. Mackby*, 261 F.3d 821, 827–28 (9th Cir. 2001) (the "causation" element under the FCA, such as it is, "is satisfied if a person 'presents, or causes to be presented,' a false or fraudulent claim" or assists in doing so). In other contexts, courts refer to the concept of "causation" in an FCA case as an aspect of materiality, i.e. that a representation is material if it causes the claim to be paid. *See, e.g., Campie*, 862 F.3d at 902.

There is no separate element of proof in an AKS-FCA case establishing a direct causal connection between the underlying violation and the submission of a claim. As explained above, the AKS itself forecloses that idea. By definition, a claim resulting from an AKS violation "**constitutes a false claim**…." 42 U.S.C. § 1320a-7b(g) (emphasis added). The AKS violation **causes** claims to be FCA violations.

Thus, it is widely held that any claim tainted by an AKS violation is false. *See Kester*, 41 F.Supp.3d at 335 (the AKS makes "clear" that the "taint of falsity" renders "any claim connected in any way to an AKS violation…ineligible for reimbursement."); *Hutcheson*, 647 F.3d at 393 (claims are necessarily "ineligible for payment" when "the underlying transaction violated the [AKS]."); *Lutz*, 2017 WL 4803911, at *7 ("a claim tainted by the AKS is a false or fraudulent claim for FCA purposes."); *Celgene*, 2014 WL 3605896 at *7 (the government "clearly would not pay for claims tainted by kickbacks"); *U.S. ex rel. Bingham v. HCA, Inc.*, 2016 WL 344887 (S.D. Fla. Jan. 28, 2016); *Jacobs*, 2015 WL 5698395, at *1.

As one court recently explained, the fact that § 1320a-7b(g) references claims "resulting from a violation" of the AKS does not change this well-established law or imply an additional element of proof. In *U.S. ex rel. Bawduniak v. Biogen Idec., Inc.*, 2018 WL 1996829 (D. Mass. Apr. 27, 2018), the defendant argued that the "resulting from" language implied a need to prove "links between a fraudulent scheme and a false claim" because the claims were "caused by, influenced by, or connected to" the AKS violation. *Id.* at *5. The court rejected that argument, as it would have required the court to conclude that Congress intended to narrow the scope of potential liability under the FCA when it inserted § 1320a-7b(g). The

legislative history and consistent judicial treatment "leads to the opposite conclusion." *Id.*

B. If any such proof required, only some factual "link" is needed rather than direct causation.

Defendants' causation argument principally relies on *U.S. ex rel. Greenfield v. Medco Health Solutions*, 880 F.3d 89 (3d Cir. 2018). Defendants overstate its holding.

Greenfield did not reject the idea that claims tainted by AKS violations are false claims. To the contrary, the court acknowledged that many courts have "expressly stat[ed] that causation is not required" in FCA cases predicated on AKS violations. 880 F.3d 89, 97 n.7 (3d Cir. 2018). *Greenfield* agreed that requiring FCA claimants to prove "direct causation" in AKS cases would "dilute" the FCA and AKS, "neither" of which requires such strict proof. *Id.* at 97. Far from rejecting the idea that "tainted" claims are actionable false claims, the court explained its rejection of a direct causation requirement by reference to its prior holding in *Wilkins*, that "[t]he Government does not get what it bargained for when a defendant is paid…for services **tainted by a kickback**." *Id.* (emphasis added) (citing *U.S. ex rel. Wilkins v. United Health Group., Inc*., 659 F.3d 295, 314 (3d Cir. 2011). Causation is not the question because the attempt to induce referrals need not exceed. The "outcome is the same" either way. *Id.*

Notably, the relator in *Greenfield* did not allege a fraudulent kickback scheme where "the underlying transaction violated the [AKS]," (*Hutcheson, supra*), or where claims arose from "improper" or "prohibited" relationships (*Bingham* and *Jacobs*, *supra*). Instead, the defendant was accused of a series of traditional kickbacks, i.e. direct monetary payments, disguised as donations to an organization in a position to direct referrals. *Greenfield*, 880 F.3d at 89–93. Even though the entire organization was not alleged to be fraudulent, the relator argued that all related claims were false because they took place around the same time as the donations. *Id.* Under these facts, *Greenfield* explained that mere temporal proximity between the donation and referrals was not enough to establish a kickback. Some "link" was required, but "less than" a direct causal link. *Id.* at 95–98.

Defendants are thus mistaken that *Greenfield* rejected the well-established principle that the FCA is violated when a healthcare provider submits claims tainted by the AKS.

C. If causation is an issue, it is a jury question.

This case is not remotely analogous to *Greenfield*, where the best the relator could muster to show that the claims were tainted was a temporal proximity.

There is direct evidence in this case that Defendants bargained over

patient referrals, reduced their understanding to an agreement, and took steps to implement that agreement. No circumstantial inferences are required because Defendants directly "linked" their AKS violations to radiology scans performed at AMI and BDH.

It is for the jury to quantify the number of false claims submitted by deciding which claims were tainted. *See Celgene*, 226 F.Supp.3d 1032 (circumstantial evidence that defendants engaged in a "systematic" kickback scheme was sufficient to raise a jury question and did not require proof of causation of specific claims); *U.S. ex rel. Colquitt v. Abbott Labs.*, 2016 WL 80000 (N.D. Tex. Jan. 7, 2016) (sufficient evidence of causation existed if defendant's conduct was a "substantial factor" in causing the presentment of the claim).

CONCLUSION

Defendants did not carry their initial burden. Their arguments misconstrue the governing law and allege Relators have failed to meet standards that do not apply. In any case, they did not remotely carry their ultimate burden of persuasion either. This is not a run-of-the-mill fraud case, but the rare one where the participants made contemporaneous records of what they were doing and why. There is substantial evidence that—at a minimum—establishes genuine disputes as to each element of

Relators' claims under *any* standard. The jury must evaluate the evidence and decide. Defendants' motion should be denied.

DATED this 13th day of July, 2018.

/s/ **Ben Alke**
Robert K. Baldwin
J. Devlan Geddes
Benjamin J. Alke
Jeffrey J. Tierney

GOETZ, BALDWIN & GEDDES, P.C.
Attorneys for Relators

CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1(d)(2)(E) and this Court's Order (Doc. 406), I certify that the foregoing document is printed with proportionately spaced typeface (Arial) of 14 points; is double-spaced; and the total word count of Relators' summary judgment response briefs is less than 15,000 (this brief includes7,666 words, including 7,633 as calculated by Microsoft Word and 33 manually-counted words in the inserted image), excluding the Caption, Tables of Contents and Authorities, and this Certificate of Compliance.

DATED this 13th day of July, 2018.

/s/ **Ben Alke**
Robert K. Baldwin
J. Devlan Geddes
Benjamin J. Alke
Jeffrey J. Tierney

GOETZ, BALDWIN & GEDDES, P.C.
Attorneys for Relators